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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,969

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Tomoharu Suga

602129-001

2010

84310

7590

07/07/2009

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,969	Applicant(s) SUGA ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' remarks and petition for extension of time, both filed on 9 April 2009.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mizumoto, et. al. (U.S. Patent No. 5,576,014).

Mizumoto, et. al. disclose an intraorally rapidly disintegrating tablet (see col. 1, lines 9-28).

The disclosed tablet is the instant tablet as claimed:

- the active ingredient mixed with a sugar of instant claim 6 (see col. 12, lines 24-26);
- the core granule coated with a pharmaceutical disintegrating agent of instant claims 6 and 7 (see col. 7, lines 19-46; col. 13, lines 39-43);
- the active ingredient of instant claims 6 and 7 (see col. 12, lines 23-26);
- the “substantially complete” covering of instant claims 6 and 7 (*i.e.* the high moldability saccharide coating (see col. 13, lines 5-7) mixed with disintegrating agents (see col. 13, lines 36-41 and lines 58-65);

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- the disintegrating agent of instant claims 2 and 8 (see col. 13, line 40);
- the sugar of instant claim 3 (see col. 7, lines 19 and 20);
- the average particle diameter of instant claims 4 and 9 (see col. 7, lines 50 and 51); and
- the tablet thickness of instant claims 5 and 10 (see col. 5, line 37).

* * * * *

Response to Arguments

Applicants' arguments filed 9 April 2009 have been fully considered and are not persuasive.

Applicants argue that the coating of the instant invention does not comprise a mixture of water, a binding agent, a sugar and a disintegrant because a disintegrating agent in a dry-powder state is added gradually to a fluidized bed granulation dryer when the volume of the binder solution has been reduced to 1/3. As the granulating step and the drying step are simultaneously carried out in the fluidized bed granulation dryer, the surface of the core is substantially not wet when the volume of the binder solution is reduced to 1/3. See remarks, page 2.

Examiner respectfully submits that when the disintegrating agent is added (e.g., see Example 1 of the instant specification), 1/3 of the binder solution still remains. That 1/3 binder solution contains water. As such, the disintegrating agent is being directly added to water. The drying step occurs only after the disintegrating agent (e.g. corn starch - see Example 1 of the instant specification) has been added to the fluid bed granulation dryer containing—1/3 binder solution. As such, examiner respectfully

submits that the coating of Mizumoto reads on the instant application, as currently claimed.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615